



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/533,941

10/25/2005

Dirk Wybe Grijpma

5100-000015/US

9691

30593 7590 12/23/2008
HARNESS, DICKEY & PIERCE, P.L.C.
P.O. BOX 8910
RESTON, VA 20195

EXAMINER

MCCLENDON, SANZA L

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,941	Applicant(s) GRIJPMA ET AL.	
	Examiner Sanza L. McClendon	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4 and 7-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-1-2, 4 and 7-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. In response to the Amendment received on November 24, 2008, the examiner has carefully considered the amendments. The examiner acknowledges the cancellation of claims 3 and 6.

Response to Arguments

3. Applicant's arguments with respect to claims 1-2, 4, and 7-24 have been considered but are moot in view of the new ground(s) of rejection. The indicated allowability of claims 5, 7 and 22 is withdrawn in view of the newly discovered reference(s) to Schappacher et al (Biomaterials, 2001) , Gross et al (6,093,792), Wang et al (J of Poly. Sci, part A, 1998), and Zhu et al (Macromol. 1991). Rejections based on the newly cited reference(s) follow.

Claim Objections

4. Claim 1 is objected to because of the following informalities: polyethylene oxide and polyethylene glycol are the same compound. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such

that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-2, 4 and 7-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritter et al (4,496,446) in view of Schappacher et al (Biomaterials, 2001) , Gross et al (6,093,792), Wang et al (J of Poly. Sci, part A, 1998), and Zhu et al (Macromol, 1991).

Ritter et al teaches irradiating structural surgical elements with gamma radiation to improve properties such as initial strength, in vivo strength and degradation loss rate of said strength properties. Said surgical elements are made of bioabsorbable polymers, such as polyglycolides and copolymers of glycolides with trimethylene carbonate—column 10, line 48. Ritter et al discloses the use of gamma radiation dosages of up to 10 Mrad (100 kGy). In addition, Ritter et al teaching ethylene oxide sterilization of said structural surgical devices—see column 4, lines 35 to 40. Ritter et al fails to teach homopolymers of TMC and copolymers of TMC with polyethylene oxide, polyethylene glycol and caprolactone. However homopolymers and copolymers of TMC with PEO, PEG and caprolactone for use in biomedical applications are known as can be evidenced by Schappacher et al, Gross et al, Wang et al, Sodergard et al, and Zhu et al. Schappacher et al sets forth homo- and co-polymers of TMC with e-caprolactone as biomedical nerve guides. Gross et al sets forth copolymers of TMC with other lactones, such as e-caprolactone as bioresorbable copolymers for use in biomedical applications. Wang et al sets forth copolymers of TMC with polyethylene glycol which can be used in biomedical applications, such as sutures. Zhu et al sets forth homopolymers of biodegradable TMC. None of the secondary references teach the use of gamma radiation crosslinking, however the examiner deems that it well within the skill level of a ordinarily skilled artisan to use the method of Ritter et al, that is exposing bioabsorbable polymers comprising TMC to improve the mechanical properties, to improve on other known copolymer of TMC, such as those taught by the secondary references, to improve the mechanical properties. The rational being it is obvious to apply a known technique, in this case crosslinking bioabsorbable copolymer

of TMC via radiation to improve mechanical properties, to a known product, in this case copolymer of TMC (other than those taught by Ritter et al) for biomedical usages, to yield predictable results. At the very least the examiner deems that it would have been at least "obvious to try" crosslinking other copolymer

Regarding the properties as found in claims 12-14, the combination of references renders the claimed invention as written obvious and therefore it is deemed the properties should be inherent to the irradiated devices of combination. And since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's composition differs and, if so, to what extent, from the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Regarding the products of claims 16, 18 and 23-24, the courts have held where the prior art discloses product that appears to be either identical with or only slightly different from product claimed in product-by-process claim; Patent Office can require applicant to prove that prior art products do not necessarily or inherently possess characteristics of his claimed product; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same; Patent Office that has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be inherent characteristic of prior art, possesses authority to require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on.

Regarding claim 22, Ritter et al teaches sterilization in a gas chamber under pressure. This is deemed to read on applicant's claim 22 since and autoclave is a vessel providing a gas under pressure to affect sterilization-PTO-892.

7. Claims 1-2, 4, 7-21 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roby et al (5,889,075) in view of Schappacher et al (Biomaterials, 2001), Gross et al (6,093,792), Wang et al (J of Poly. Sci, part A, 1998), and Zhu et al (Macromol., 1991).

Roby et al sets forth irradiated surgical sutures and methods of making them. Said surgical sutures are fabricated from a copolymer of dioxanone, trimethylene

carbonate, and glycolide, which is treated with gamma irradiation to enhance the properties. Said copolymers can be arranged in sequences as found in columns 2, lines 59-68 to column 3, and lines 1-14. The irradiation treatment is from a total dose rate from about 2 to about 12 Mrad in an inert atmosphere while under vacuum. Thus the examiner deems claims 10 and 11 are envisioned in the reference.

Roby et al fails to teach homopolymers of TMC and copolymers of TMC with polyethylene oxide, polyethylene glycol and caprolactone. However homopolymers and copolymers of TMC with PEO, PEG and caprolactone for use in biomedical applications are known as can be evidenced by Schappacher et al, Gross et al, Wang et al, Sodergard et al, and Zhu et al. Schappacher et al sets forth homo- and co-polymers of TMC with e-caprolactone as biomedical nerve guides. Gross et al sets forth copolymers of TMC with other lactones, such as e-caprolactone as bioresorbable copolymers for use in biomedical applications. Wang et al sets forth copolymers of TMC with polyethylene glycol which can be used in biomedical applications, such as sutures. Zhu et al sets forth homopolymers of biodegradable TMC. None of the secondary references teach the use of gamma radiation crosslinking, however the examiner deems that it well within the skill level of a ordinarily skilled artisan to use the method of Ritter et al, that is exposing bioabsorbable polymers comprising TMC to improve the mechanical properties, to improve on other known copolymer of TMC, such as those taught by the secondary references, to improve the mechanical properties. The rational being it is obvious to apply a known technique, in this case crosslinking bioabsorbable copolymer of TMC via radiation to improve mechanical properties, to a known product, in this case copolymer of TMC (other than those taught by Ritter et al) for biomedical usages, to yield predictable results. At the very least the examiner deems that it would have been at least "obvious to try" crosslinking other copolymer

Regarding the properties as found in claims 12-14, the combination of references is deemed to render the claimed invention as written obvious and therefore it is deemed the properties should be inherent to the irradiated devices of combination. And since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's composition differs and, if so, to what extent, from the discussed reference. Therefore, with the showing of the

reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Regarding the products of claims 16, 18 and 23-24, the courts have held where the prior art discloses product that appears to be either identical with or only slightly different from product claimed in product-by-process claim; Patent Office can require applicant to prove that prior art products do not necessarily or inherently possess characteristics of his claimed product; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same; Patent Office that has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be inherent characteristic of prior art, possesses authority to require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanza L. McClendon whose telephone number is (571) 272-1074. The examiner can normally be reached on Monday through Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1796

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sanza L McClendon/
Primary Examiner, Art Unit 1796

SMc